

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

IN THE CLAIMS

The pending claims are reproduced below. Please presently cancel claims 13, and 66-82. Please presently amend claims 15, 17-20, 23-27, 29-34, and 39-41. Please add new claim 92.

Claims 1-12 (cancelled)

13. (Presently cancelled) A method of passively immunizing a human or non-human animal subject against a preselected antigen by administering an immunoglobulin produced by transgenic plant cells, said method comprising administering to said subject a prophylactic amount of a formulation comprising an antigen-specific immunoglobulin molecule which specifically binds to said preselected antigen or immunologically active fragment of the antibody, said formulation obtained by processing plant cells containing nucleotide sequences encoding an immunoglobulin heavy chain polypeptide and an immunoglobulin light chain polypeptide wherein said nucleotide sequences also encodes a leader sequence for each polypeptide; and antigen specific immunoglobulin product encoded by said nucleotide sequences, wherein each leader sequence forms a secretion signal that is cleaved from each of said immunoglobulin heavy chain and light chain polypeptides following proteolytic processing.

Claims 14 (cancelled)

15. (Presently amended) The method of claim 92 [~~13~~], wherein said immunoglobulin molecule is administered as part of a composition, which composition further comprises a material having nutritional value.

16. (Previously pending) The method of claim 15, wherein said material having nutritional value is from a plant or an animal.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

17. (Presently amended) The method of claim 92 [43], wherein said immunoglobulin molecule is administered as part of a composition, which composition further comprises a physiologically inert material.
18. (Presently amended) The method of claim 92 [43], wherein said immunoglobulin heavy chain is a fragment of a full-length heavy chain.
19. (Presently amended) The method of claim 92 [43], wherein said immunoglobulin light chain is a fragment of a full length light chain.
20. (Presently amended) The method of claim 92 [43], wherein said preselected antigen is from a pathogen.
21. (Previously pending) The method of claim 20, wherein said pathogen is selected from bacterial, viruses, or parasites.
22. (Previously pending) The method of claim 20, wherein the pathogen is E. Coli, Salmonellae, Vibrio cholerae, or Salmonellae typhimurium.
23. (Presently amended) The method of claim 92 [43], wherein the plant cells are from a monocot.
24. (Presently amended) The method of claim 92 [43], wherein the plant cells are from a dicot.
25. (Presently amended) The method of claim 92 [43], wherein the leader sequence is a non-native leader sequence.
26. (Presently amended) The method of claim 92 [43], wherein the leader sequence is a yeast leader sequence.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

27. (Presently amended) The method of claim 92 [~~13~~], wherein the leader sequence is a plant leader sequence.

28. (Cancelled)

29. (Presently amended) The method of claim 92 [~~13~~], wherein the immunoglobulin heavy chain comprises at least a portion of a constant region and said constant region is from an IgA heavy chain.

30. (Presently amended) The method of claim 92 [~~13~~], wherein the immunoglobulin heavy chain comprises at least a portion of a constant region and said constant region is from an IgG heavy chain.

31. (Presently amended) The method of claim 92 [~~13~~], wherein said heavy chain is full length.

32. (Presently amended) The method of claim 92 [~~13~~], wherein said light chain is full length.

33. (Presently amended) The method of claim 92 [~~13~~], wherein said immunoglobulin molecule is glycosylated and free from detectable sialic acid residues.

34. (Presently amended) The method of claim 92 [~~13~~], wherein said immunoglobulin molecule is a fragment of a full-length immunoglobulin.

35. (Previously pending) The method of claim 34, wherein said fragment is a Fab.

36. (Previously pending) The method of claim 34, wherein said fragment is a Fab'.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

37. (Previously pending) The method of claim 34, wherein said fragment is a $F(ab')_2$.
38. (Previously pending) The method of claim 34, wherein said fragment is an F_v .
39. (Presently amended) The method of claim 92 [43], wherein the plant cells are alga cells.
40. (Presently amended) The method of claim 92 [43] wherein said plant cells are in the form of a plant.
41. (Presently amended) A method of passively immunizing a human or non-human animal subject against a preselected antigen by administering an immunoglobulin produced by transgenic plant cells, said method comprising ~~administering to said subject a formulation comprising a prophylactic amount of an antigen-specific immunoglobulin, said formulation obtained~~ obtaining a formulation comprising an antigen-specific immunoglobulin by processing plant cells containing nucleotide sequences encoding an immunoglobulin heavy chain and an immunoglobulin light chain wherein said nucleotide sequences also encode a leader sequence for said heavy chain and said light chain and wherein each leader sequence forms a secretion signal that is cleaved from each of said immunoglobulin heavy chain and light chain polypeptides following proteolytic processing and administering to said subject a prophylactic amount of said formulation comprising said antigen-specific immunoglobulin produced from transgenic plants.
42. (Previously pending) The method of claim 41, wherein said immunoglobulin heavy chain is a fragment of a full-length heavy chain.
43. (Previously pending) The method of claim 41, wherein said heavy chain is full length.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

44. (Previously pending) The method of claim 41, wherein said immunoglobulin light chain is a fragment of a full length light chain.

45. (Previously pending) The method of claim 41, wherein said light chain is full length.

46. (Previously pending) The method of claim 41, wherein said heavy chain and said light chain are full length.

47. (Previously pending) The method of claim 41, wherein said heavy chain is a fragment of a full length heavy chain and said light chain is a fragment of a full length light chain.

48. (Previously pending) The method of claim 41, wherein said heavy chain includes at least a portion of a constant region and wherein said constant region is from an IgA antibody.

49. (Previously pending) The method of claim 41, wherein said heavy chain includes at least a portion of a constant region and wherein said constant region is from an IgG antibody.

50. (Previously pending) The method of claim 41, wherein said heavy chain includes at least a portion of a constant region and wherein said constant region is from an IgM antibody.

51. (Previously pending) The method of claim 41, wherein said immunoglobulin molecule is glycosylated and free from detectable sialic acid residues.

52. (Previously pending) The method of claim 41, wherein said immunoglobulin is a fragment of a full-length immunoglobulin.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

53. (Previously pending) The method of claim 52, wherein said fragment is a Fab.
54. (Previously pending) The method of claim 52, wherein said fragment is a Fab'.
55. (Previously pending) The method of claim 52, wherein said fragment is a F(ab')₂.
56. (Previously pending) The method of claim 52, wherein said fragment is an Fv.
57. (Previously pending) The method of claim 41, wherein said preselected antigen is from a pathogen.
58. (Previously pending) The method of claim 57, wherein said pathogen is selected from bacteria, viruses, or parasites.
59. (Previously pending) The method of claim 47, wherein said pathogen is E. Coli, Salmonellae, Vibrio cholerae, or Salmonellae typhimurium.
60. (Previously pending) The method of claim 41, wherein the plant cells are from a monocot.
61. (Previously pending) The method of claim 41, wherein the plant cells are from a dicot.
62. (Previously pending) The method of claim 41, wherein the plant cells are from an alga.
63. (Previously pending) The method of claim 41, wherein the leader sequence is a non-native leader sequence.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

64. (Previously pending) The method of claim 41, wherein said immunoglobulin is formulated with a pharmaceutically acceptable carrier.

65. (Previously pending) The method of claim 41, wherein said plant cells are in the form of a plant.

66-82 (Presently cancelled).

83. (Previously pending) A method of passively immunizing a human or non-human animal subject against a preselected antigen by administering an immunoglobulin produced by transgenic plant cells, said method comprising:

(a) preparing plant cells containing

nucleotide sequences encoding a dual chain immunoglobulin product comprising an immunoglobulin heavy chain and an immunoglobulin light chain wherein said nucleotide sequences also encode a leader sequence for each of said heavy chain and light chain, and antigen-specific immunoglobulin encoded by said nucleotide sequence, wherein the leader sequence forms a secretion signal that is cleaved from each of said immunoglobulin light and heavy chain following proteolytic processing;

(b) isolating antigen specific immunoglobulin from the plant cells; and

(c) administering to said subject a prophylactic amount of said antigen specific immunoglobulin.

84. (Previously pending) The method of claim 83, wherein said antibody is full length.

85. (Previously pending) The method of claim 83, wherein said immunoglobulin is a fragment of a full-length immunoglobulin.

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

86. (Previously pending) The method of claim 83, wherein said heavy chain includes at least a portion of a heavy chain constant region and wherein said constant region is from an IgM antibody.

87. (Previously pending) The method of claim 83, wherein said heavy chain includes at least a portion of a constant region and wherein said constant region is from an IgG antibody.

88. (Previously pending) The method of claim 83, wherein said heavy chain includes at least a portion of a constant region and wherein said constant region is from an IgG antibody.

89. (Previously pending) The method of claim 83, wherein said preselected antigen is from a pathogen.

90. (Previously pending) The method of claim 89, wherein said pathogen is selected from bacteria, viruses, or parasites.

91. (Previously pending) The method of claim 89, wherein said pathogen is E. Coli, Salmonellae, Vibrio cholerae, or Salmonellae typhimurium.

92. (New) A method of passively immunizing a human or non-human animal subject against a preselected antigen using an immunoglobulin molecule produced in transgenic plants, said method comprising

(a) obtaining a source of antigen-specific immunoglobulin from transgenic plant cells producing antigen specific immunoglobulin, said plant cells containing nucleotide sequence encoding an immunoglobulin heavy chain polypeptide and an immunoglobulin light chain polypeptide wherein said nucleotide sequences also encodes a leader sequence for each polypeptide wherein each leader sequence forms a secretion signal that is cleaved

Atty. Dkt. No.: EPI3007F
(formerly TSRI 184.2C2)

from each of said immunoglobulin heavy chain and light chain polypeptides following proteolytic processing; and

(b) administering a prophylactic amount of said antigen-specific immunoglobulin molecule to said subject, thereby passively immunizing a human or non-human animal subject against a preselected antigen.